IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor	:	Leroy Braun	
Appln. No.	:	10/685,240	
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Title	:	MULTIMEDIA FEATURE FOR DIAGNOSTIC INSTRUMENTATION	Examiner: J. Chapman
Docket No.	:	M33.12-0024	

DECLARATION OF ROGER C. THEDE UNDER 37 C.F.R. 1.132

Commissioner For Patents
P.O. Box 1450
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I, Roger C. Thede, state:

1 I am a person who is skilled in the art of electronics design, including analog and digital hardware design, software design, and algorithm development.

2. I have over 25 years of experience as an Electrical Engineer, primarily in the area of software and hardware design. I have a Bachelors of Science degree in Electrical Engineering from the University of Wisconsin, Madison. I have also taken graduate level courses in the Electrical Engineering field from the University of Minnesota, earning 25 graduate level credits. I am a Minnesota Licensed Professional Engineer and an inventor or co-inventor on 19 different patents.

3. I am currently employed as a Design Engineer with Poliac Research Corporation of Burnsville, MN. Poliac Research Corporation provides embedded software and hardware development services, technology development services, and complete product development services for medical, telecommunications, industrial automation, and other technology companies.

4. I have reviewed claims 6-15 of U.S. Application No. 10/685,240 (attached as Appendix A).

5. I have reviewed Japanese Publication No. JP 7 308310 ("the '310 publication) and the RION AA-75 Operating Manual ("the RION manual").

6. Based on my review of the '310 publication and the RION manual, these documents disclose an audiometer system that delivers test tones to a test subject according to a logical testing procedure, interrupts testing when an error in responses by the test subject is detected, and requires intervention by a human test administrator to explain to the test subject how to correctly provide responses in the future to avoid the error that occurred, and also to assess and execute the appropriate manner for resuming or restarting the hearing test.

7. In my opinion, claims 6-15 of U.S. Application No. 10/685,240 are directed to a system in which an output is automatically switched from test tones, to instructions represented by sound waves produced by a computer in response to a detected error in responses to the test tones, and back to test tones after the instructions have been provided, without human intervention.

8. Based on my review, the '310 publication and the RION manual do not disclose a system that automatically switches from outputting test tones to outputting computer-generated instructions when an error is detected, and back to outputting test tones after the instructions have been provided. Rather, switching back to outputting test tones after interrupting a hearing test is performed in the '310 publication and the RION manual by a test administrator who must manually restart the test.

9. Based on my review, the '310 publication and the RION manual disclose a system in which a routine for handling errors is provided that involves providing a test tone at an increased volume level if the patient continued to press a response button after the test tone is discontinued. See paragraphs 62

and 63 of the '310 publication, and paragraph 8 of the RION manual. This routine does not involve switching from outputting test tones to outputting corrective instructions, and then switching back to outputting test tones after the corrective instructions have been delivered.

10. Based on my review, the '310 publication and the RION manual teach that whenever the system switches from outputting test tones to outputting a notification of an error condition, such as via a message on a display and/or an alarm, a human test administrator is required to manually resume testing by pressing a button that switches back to outputting test tones. See paragraphs 43, 65 and 75 of the '310 publication, and paragraph 9 of the RION manual.

11. In my opinion, and based on my review, there is no suggestion in the '310 publication or in the RION manual to modify the error handling routine that provides a test at an increased volume level (see paragraph 9 above) with the error handling routine that switches the output of the system from test tones to a notification of an error condition (see paragraph 6 above). I am not aware of any other reference that would suggest such a modification.

12. In my opinion, and based on my review, if the modification discussed in paragraph 11 were to be made, the teachings of the '310 publication and the RION manual would dictate that switching back from the notification of an error condition to outputting test tones would require a human test administrator to manually resume testing by pressing a button. See paragraph 10 above.

13. In my opinion, and based on my review, it would not have been obvious to a person skilled in the art of electronics and software design to modify the algorithm performed by the system described in the '310 publication and the RION manual so that resumption of testing following interruption and error notification could be done automatically under computer control, as recited in

claims 6-15 of U.S. Application No. 10/685,240. Specifically, in order to do this, a designer would have had to attempt to create a flow chart in hardware and/or software of an entire series of test procedures, having within it decision points where all possible test subject errors and instructions that would be effective to correct those errors could be determined specifically and unequivocally (to account for the fact that the human judgment of a test administrator would not be available). An automated message would then need to be displayed or played, with full confidence based on the definition of the flow chart that the nature of the error has been precisely identified and that appropriate instructions can be given to correct the error. Finally, a decision of how to continue testing would have to be made by the system. In my opinion, this modification would have required expertise in how tests are administered together with an in-depth knowledge of all types of errors which might be committed by any given test subject, the sequence of events which could produce those errors, and what additional instruction would effectively correct the test subject's behavior. The expertise of an experienced audiologist and test administrator would need to be designed into the algorithm to create an effective and useful method for automatedly administering an audiometric test. Incorporating this expertise and intelligence into a hardware and/or software design would have required extensive effort, experimentation, testing and expertise, in view of the lack of a suggestion in the '310 publication, the RION manual or elsewhere in the art of how this might be done.

I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statement were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Roger C. Thede

Date: 1/30/06

APPENDIX A

6. A multimedia audiometer comprising:

audio circuitry capable of generating audible test tones for delivery to earphones worn by a test subject;

a computer selectively operable to produce instructions represented by sound waves for delivery to the earphones, the computer being operatively coupled to the audio circuitry;

microprocessor circuitry operatively coupled to the computer, the microprocessor circuitry including a central processing unit (CPU) and a memory;

an interface operatively coupled to the computer and the microprocessor circuitry for signaling whether the test subject perceives the audible test tones generated by the audio circuitry;

a switch having a first state in which audible test tones generated by the audio circuitry are provided to the earphones, and a second state in which the instructions represented by sound waves produced by the computer are provided to the earphones; and

software stored in at least one of the computer and the memory of the microprocessor circuitry, the software operating the computer, the microprocessor circuitry, the audio circuitry and the interface to generate the audible test tones for delivery to the earphones, monitor responses by the test subject, detect errors in the test subject's responses, selectively produce the instructions for delivery to the earphones in response to the detected errors, and to control the switch to switch to the second state when errors are detected in the test subject's responses and to automatically switch back to the first state following delivery of the instructions to the earphones so that testing is resumed without human intervention.

7. The multimedia audiometer of claim 6, wherein the responses of the test subject are compiled and stored in at least one of the computer and the memory of the microprocessor circuitry.

8. The multimedia audiometer of claim 7, wherein the software operates the computer, the microprocessor circuitry, the audio circuitry and the interface according to a pre-programmed logical testing procedure.

9. The multimedia audiometer of claim 8, wherein the logical testing procedure is the Hughson-Westlake procedure.

10. The multimedia audiometer of claim 6, wherein the software is stored in the computer.

11. The multimedia audiometer of claim 6, wherein the software is stored in the memory of the microprocessor circuitry.

12. A computer adapted to perform an audiometric test of a subject, comprising:

a test tone generator operable to deliver audible test tones to earphones worn by the subject;

an input/output interface; and

software programmed to control the test tone generator to deliver the audible test tones to the earphones worn by the subject, monitor responses by the subject received over the input/output interface, detect errors in the subject's responses, selectively deliver audible corrective instructions to the earphones in response to the detected errors, and automatically resume delivery of the audible test tones after the audible corrective instructions are delivered without human intervention.

13. The computer of claim 12, wherein the software is operable to compile the responses of the subject and store results of the audiometric test.

14. The computer of claim 13, wherein the software is operable to display and/or print the results of the audiometric test.

15. The multimedia audiometer of claim 6, wherein the switch comprises a relay circuit.